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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/821,025	03/19/1997	HENDRIK LOUIS BIJL	246152006900	3574
25225	7590	08/23/2005		
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/821,025	Applicant(s) BIJL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-114 is/are pending in the application.
- 4a) Of the above claim(s) 96-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-95 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.0.2

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/05 has been entered.

Newly submitted claims are directed to a non-elected invention. See applicant's election filed April 27, 1998 wherein the Group II, directed to the composition was elected.

Accordingly, claims 96-113 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 68-95 and 114 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-95 and 114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claims 81 and 82 of *Mortierella* containing tetra-acetyl-phyto sphingosine or a for *Mortierella* containing vitamin.

In addition no basis or support is found in the present specification for the range of the sizing of granules, wherein the granules are *Mortierella* granules. It is noted that "granules" having 12 mm are large and granules wherein the length is 2-6 times the diameter are very large. The specification indicates that granules especially from a fungal biomass can have a diameter from 0.3 to 10 mm, preferably a diameter of from 0.7 to 5 mm, optionally from 1 to 3 mm (Specification, page 21, paragraph 2). The specification also indicates that when using extrusion the granules may be roughly cylindrical in shape (page 19, paragraph 6).

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In addition, the *Mortierella* granules actually obtained in Examples 9 and 10 used a die plate of 1.8, 2.0 and 2.2 mm. In example 12, the diameter of the holes was about 2 mm and the diameter of the particles was also about 2 mm. In example 14 the diameter of the extruded biomass was 1.3 mm.

Therefore this material constitutes new matter and should be deleted.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68-95 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto *et al.* (U.S. Patent No. 4,916,066) taken with Barclay (U.S. Patent No. 5,656,319) and Huang *et al.* (U.S. Patent No. 4,0566,38)

Akimoto *et al.* teach a dry *Mortierella* composition (See, e.g., col. 8, lines 7-12). The reference differs from the claimed invention in that the dried composition is not in extruded granule form. However, Barclay teaches a related microbial composition containing fatty acids wherein the composition is extruded. See, e.g., bridging paragraph between col. 11 and 12.. The reference recognizes the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion. In addition, Huang *et al.* teach extruded granules of fungi such as *Aspergillus* which are subsequently dried. See, e.g., bridging paragraph between col. 2 and 3, and col. 3, lines 11-17. The extruded material would reasonably be expected to be porous as claimed, to have the degree of dryness required and to have the dimensions as claim designated.

The properties of the dried *Mortierella* as far as oil content and sizing discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of composition properties for optimization purposes identified as result-effective

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variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the dried *Mortierella* product of Akimoto *et al.* by submitting the biomass to an extrusion and drying process as disclosed by Barclay and Huang *et al.* in view of the expected economic benefits of obtaining a dried stable microbial product that is easy to manipulate and the cost of which is reduced.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

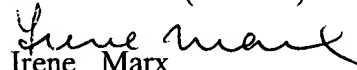
Applicants' arguments are moot in view of the new grounds of rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651